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10/525,512	02/24/2005	Naohiro Soga	SHM-022	7865

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EXAMINER	
LIAO, DIANA J	

ART UNIT	PAPER NUMBER
1793	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,512	SOGA ET AL.	
	Examiner	Art Unit	
	DIANA J. LIAO	1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *6 and 7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Amended claims 1-5 and new claims 8 and 9 are pending. Claims 6 and 7 have been withdrawn. Amendment and remarks filed on 12/31/07 have been considered.

Claim Rejections - 35 USC § 102 and 103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nakanishi, et al. (US 5,624,875) with Nakanishi, "Pore Structure Control of Silica Gels" (1997) to show an inherent state of fact.

Nakanishi '875 teaches a process for producing materials for possible use as a filter for separating blood, a catalyst, or an enzyme support. The material bears interconnected continuous macropores with a median diameter larger than 0.1 μm. (see abstract) The possible usage of the material as a filter inherently teaches that fluid must be able to pass through the pores. The interconnected macropores are preferably of median diameters from 0.2-20 μm, and the volume percent is typically above 50%. (col 6, lines 40-52) The materials can be made using a sol-gel method which involves the hydrolysis of a metalorganic compound, solidifying through a sol-gel transition, removing the liquid phases, and firing the gel. (col 3, lines 15-27) Metal alkoxides are most commonly used for the process (col 4, line 26-27) and even more preferred are silicon alkoxides such as tetramethoxysilane, tetraethoxysilane and polymerized derivatives. (col 5, lines 61-63) The pores may be modified to contain a functional organic ligand, enzyme, or catalyst metal (claim 10), creating reactivity on the surface of the pores. More specifically mentioned are octadecyl ligands, glucose isomerase, platinum and palladium. (col 6, line 65 - col 7, line 3) The sol-gel creation process is also performed under certain conditions, e.g. with nitric acid (col 4, lines 40-45), which contains reactive sites, in order to speed up the reaction.

Nakanishi '875 does not teach a backbone of metaloxane bonds and hydrocarbon chains. However, this property is considered inherent upon review of Nakanishi "Pore Structure Control of Silica Gels". The sol-gel process is made up of hydrolysis and condensation reactions which are known to occur simultaneously to form a network of metaloxane bonds. (page 69) The sol-gelling process cannot occur without hydrolysis and condensation, which is what causes the mixture to gel. Unreacted alkoxy chains are present when the water to alkoxide ratio is below 2. (page 69) Alkoxy chains are primarily comprised of hydrocarbon chains. The ratio is below 2 in example 5 of Nakanishi '875. (col 10, lines 2-6) Therefore, it is inherent that the sol-gel method performed in Nakanishi '875 produces a product with a backbone of metaloxane bonds and hydrocarbon chains.

Nakanishi '875 teaches a process comprising the addition of a component with a reactive site (such as nitric acid) to a sol-gel reaction mixture, and a phase separation and sol-gel transformation, eventually yielding a porous material with reactive surfaces in the form of functional organic ligands, enzymes, or catalyst metals. Nakanishi '875 teaches that the product has interconnecting macropores with a median diameter of preferably 0.2-20 μm (200-20000nm) and that the macropore volume typically exceeds 50%. Nakanishi '875 also teaches the use of a component with a reactive site such as the acid catalyst used in its production. There are also other reactive groups attached to the pores of the final product such as octadecyl, enzymes, and metal catalysts, which would yield additional reactivity on the surface of the product. Therefore, claims 1, 2, and 4 are not found patentable over the prior art.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi, et al. (US 5,624,875) in view of Allen, et al. (US 6,334,856).

Nakanishi '875 teaches a form of the product of the process disclosed to be a rod that will be used in conjunction with an injector or a catheter for blood injection. (col 13, lines 33-35)

Nakanishi '875 does not teach a material which formed in a column shape with a covered side surface, in a capillary of a diameter of 1mm or less or in a groove with a width of 100 μm or less.

However, it would be obvious to one of ordinary skill in the art to create a porous support of that size. Allen '856 teaches microneedles that are applied through use of a catheter or laparoscope. (col 4, lines 5-8) The cross sectional diameters of these microneedles are usually between 10nm and 1mm. (col 5, lines 42-45) These microneedles can be porous due to a network of pores (col 11, lines 18-20), such as the product taught in Nakanishi '875. Allen '856 also discloses microneedles made of silicon dioxide. (col 15, lines 12-30) One would be motivated to create a small porous object out of the material taught in Nakanishi '875 because it is porous and suitable for microneedles. Since Nakanishi '875 teaches its use in biological areas and also its use in conjunction with catheters, it would be obvious to one of ordinary skill in the art to use the porous product taught in Nakanishi '875 with the size and shape taught in Allen, '856.

Therefore, it would be obvious to make an object of a diameter of 1mm or less because microneedles of silicon dioxide of that size are known in the art to be used in catheters. Claim 3 is not found patentable over the prior art.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi, et al. (US 5,624,875) in view of Rolison, et al. (US 6,492,014).

Nakanishi '875 does not teach a method of producing a monolithic reactive porous support wherein the reactive site is a surface of a find particle co-existing during a sol-gel reaction.

However, it would still be obvious to one of ordinary skill in the art to put in a reactive site, e.g. platinum or palladium, in as a fine particle during a sol-gel reaction in view of Rolison '014. Rolison '014 teaches the production of a composite aerogel or xerogel made from the condensation and hydrolysis of metal alkoxide precursors. (col 1, lines 15-17) creating a porous network (col 2, lines 53-55) It teaches a process which allows a particulate being added to a sol-gel reaction at a time where it will not be fully encapsulated by the gel, and before a time when the gel would be too well formed to incorporate another substance without risk of it being washed away. This window is described by shortly before or shortly after the onset of gelation, which in both cases mean that the particle is present during the sol-gel reaction. (col 4, lines 43-46).

One would be motivated to combine these steps because adding the reactive site as a solution instead of in particle form, for example, would incorporate a large portion of it into the gel, where it would not be able to react with anything on the surface of the

pores. This process allows for controlled deposition of catalysts onto the surface of the gel, without losing a substantial amount from washing or leaching. (col 1, lines 46-48)

Therefore, it would be obvious to one of ordinary skill in the art to add a component in the form of a fine powder during the sol-gel reaction because incorporation in this manner would allow the catalyst to be well incorporated into the product without too much of it being fully encapsulated and rendered inactive. Claim 5 is rejected over prior art.

8. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi, et al. (US 5,624,875) in view of Rolison, et al. (US 6,492,014), Nakanishi "Pore Structure...", and Liu, et al. ("Encapsulation of protein molecules..., " 1999).

Nakanishi '875 teaches a process for producing materials for possible use as a filter for separating blood, a catalyst, or an enzyme support. The material bears interconnected continuous macropores with a median diameter larger than 0.1 μm. (see abstract) The materials can be made using a sol-gel method which involves the hydrolysis of a metalorganic compound (which is inorganic-organic), solidifying through a sol-gel transition, removing the liquid phases, and firing the gel. (col 3, lines 15-27) As discussed in a previous rejection, it is held inherent that in the sol-gel process, the main structure comprises of metaloxane bonds and hydrocarbon chains. Metal alkoxides are most commonly used for the process (col 4, line 26-27) and even more preferred are silicon alkoxides. (col 5, lines 61-63) Nakanishi '875 teaches the bonding

or support of additional functional groups or catalysts to the walls of the porous material created. (col 6, lines 63-67)

Nakanishi '875 does not teach dissolving the reactive site into a solution and then reacting the solution with a gel precursor further comprising a metal oxide. Nakanishi '875 also does not teach how the functional groups or catalysts attach to the support. Nakanishi '875 does not teach a reaction between the surface of the monolith and the reactive site between gel formation and a final drying heat treatment.

The use of an additional metal oxide would be obvious to one of ordinary skill in the art in view of Rolison '014. Rolison '014 teaches the production of highly porous aerogels and xerogels. As in Nakanishi '875, Rolison '014 utilizes a hydrolysis and condensation reaction. (col 1, lines 15-17) Rolison '014 explains that a sol is a suspension of precursor particles which can be comprised of silica sols and various metal oxide sols, such as zirconia, and alumina. (col 2, lines 49-60) Rolison '014 also teaches that most sols are based on metal oxides made from metal alkoxides. (col 5, lines 39-43) This strongly suggests that Nakanishi '875 also contains metal oxides and/or silica that are derived from the alkoxides used.

One of ordinary skill in the art would be motivated to add in other metal alkoxides and metal oxides in view of the teachings of Nakanishi, "Pore Structure...". "Pore Structure..." teaches that alkoxides based on metals other than silicon, such as titanium and aluminum, undergo sol-gel transformation much faster, creating a solid product faster without the use of as much catalyst. (page 69)

Dissolving the reactive site-containing component and reacting it before drying would be obvious to one of ordinary skill in the art in view of Liu, et al. Liu, et al. teaches the addition of proteins including that of an enzyme, in a solution. (page 4536) However, though Liu, et al. teaches the enzyme addition to be before drying, it also teaches the addition to be mainly before the gel formation step. It would be obvious to one of ordinary skill in the art to modify the enzyme addition step to occur after gel formation in view of Rolison '014. Rolison '014 teaches the addition of a reactive site containing material such as metal oxides (col 4, line 31) shortly before or shortly after the onset of gelation (col 4, lines 43-46), in either case before drying. Rolison '014 teaches that the disadvantage of adding an additional material before gel formation is that the encapsulation may reduce the reactivity of the material. (col 1, lines 32-41) The solution proposed by Rolison '014 is to add the component while or shortly after the gel begins to form.

One of ordinary skill in the art would be motivated to add, for example, an enzyme or a catalyst as a solution to the sol-gel reaction mixture after gel formation and before drying in order to incorporate it into the final product because a solution offers a homogenous medium in which to disperse the additive, and addition before drying allows for a strong bond without encapsulating the additive to the point where it is rendered ineffective.

Therefore, claims 8 and 9 are not found patentable over the prior art.

Response to Arguments

9. Applicant's arguments with respect to claims 1-5 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gonzalez Oliver, et al. (US 4,713,338) teaches a method of producing glass filtrating beads. A sol-gel process reacting alkoxides is used, a metaloxane structure is formed (claim 1), a pore size of 2-500nm is usually achieved (col 6, lines 8-11), and the beads are disclosed to be possibly used to house enzymes by binding other reactive groupings to the beads such as OH and amines (col 11, lines 41-49).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Claims 1-5 and 8 and 9 have been rejected. No claims have been allowed. Claims 6 and 7 have been withdrawn due to being the non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANA J. LIAO whose telephone number is (571)270-3592. The examiner can normally be reached on Monday - Friday 8:00am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley Silverman can be reached on 571-272-1358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ngoc-Yen M. Nguyen/
Primary Examiner, Art Unit 1793

DJL